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Radiotherapy after Oesophageal Cancer Stenting (ROCS) study

Submission date 04/07/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/07/2012	**Overall study status** Completed	
Last Edited 28/02/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-radiotherapy-oesophageal-cancer-difficulty-swallowing-rocs

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Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01915693

Protocol serial number
HTA 10/50/49, WCTU030

Study information

Scientific Title
Palliative radiotherapy in addition to self-expanding metal stent for improving dysphagia and survival in advanced oesophageal cancer: Radiotherapy after Oesophageal Cancer Stenting (ROCS) study

Acronym
ROCS

Study objectives
Radiotherapy in addition to self-expanding metal stent (SEMS) placement improves patient-reported dysphagia and increases time to progression in a patient population unable to undergo surgery.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/105049
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/81666/PRO-10-50-49.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Two-arm open randomised phase III trial with a 1:1 randomisation ratio. A qualitative component in a sub-set of patients.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophageal cancer requiring stent for relief of dysphagia

Interventions
Arm A: Self-expanding metal stents (SEMS) (Control Arm)
SEMS insertion will be undertaken in accordance with standard local protocols. Covered or partially covered metal stents will be used and the length type and mode of stent placement will be selected by the clinician. Insertion will occur within two weeks of randomisation.

Arm B: SEMS plus external beam radiotherapy (Intervention Arm)
External beam radiotherapy (EBRT) is routinely available at regional cancer centres across the UK. For palliation of dysphagia in oesophageal cancer, a radiotherapy course delivering a tumour absorbed dose of 20Gy in 5 fractions or 30Gy in 10 fractions within 4 weeks of SEMS insertion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Assess the impact of radiotherapy in addition to self-expanding metal stent (SEMS) placement on time to progression of patient-reported dysphagia in a patient population unable to undergo surgery.

Key secondary outcome(s))
1. Assess the impact of combination treatment on core components of health related quality of life
2. Assess the impact of radiotherapy in addition to SEMS placement on overall survival
3. Measure morbidity associated with the interventions
4. Measure re-intervention rates
5. Assess the cost of the addition of radiotherapy to SEMS placement

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Histological confirmation of oesophageal carcinoma excluding small cell histology
2. Not suitable for radical treatment (oesophagectomy or radical chemoradiotherapy) either because of patient choice or medical reasons
3. Dysphagia clinically assessed as needing stent as primary treatment of the dysphagia
4. Age 16 years or over
5. Discussion and treatment decision for SEMS placement made by an Upper GI multi-disciplinary team
6. Clinician assessment of ability to attend for radiotherapy
7. Expected survival of at least 12 weeks
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
220

Key exclusion criteria
1. Histology of small cell carcinoma type
2. Tumour length of greater than 12 cm
3. Tumour growth within 2 cm of the upper oesophageal sphincter
4. Endoscopic treatment of the tumour, other than dilatation, planned in the peri-stent period
5. Presence of a tracheo-oesophageal fistula
6. Presence of a pacemaker
7. Previous radiotherapy to the area of the proposed radiotherapy field
8. Planned endoscopic treatment of the tumour (e.g. laser) in the immediate peri-stenting period
9. Pregnancy

Date of first enrolment
01/10/2012

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ward 32
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Sponsor information

Organisation

Velindre NHS Trust (UK)

ROR
https://ror.org/05ntqkc30

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK), 10/50/49

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2021	22/02/2021	Yes	No
Results article		01/05/2021	28/05/2021	Yes	No
Protocol article	protocol	22/10/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			28/02/2023	No	Yes